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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/809,799

03/26/2004

Jean-Marc Beraud

04045

7168

23338

7590

12/27/2007

DENNISON, SCHULTZ & MACDONALD

1727 KING STREET

SUITE 105

ALEXANDRIA, VA 22314

EXAMINER

EREZO, DARWIN P

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

12/27/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/809,799

Applicant(s)

BERAUD, JEAN-MARC

Examiner

Darwin P. Erez

Art Unit

3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 August 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. ____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/9/04</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 8/9/04 has been received and made of record. Note the acknowledged form PTO-1449 enclosed herewith.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

3. The drawings filed on 8/9/04 are acceptable.

Specification

4. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 5, 7-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
7. Claim 5 recites the limitation of "the wall of the cavity". There is no antecedent basis for this limitation in the claim.

8. Claims 7, 8, 12 and 15 recite the limitation of "it(s)", which renders the claim vague and indefinite because the limitation does not clearly specify which structure "it" refers to.

9. Claim 10 and 11 recite the limitation "preferably", which renders the claim indefinite because a broad range or limitation followed by a linking term (e.g. preferably, maybe, for instance, especially) and a narrow range or limitation within the broad range or limitation does not clearly set forth the metes and bounds of the patent protection desired.

10. Claims 10 and 11 also recite the limitation "the arcuate portion". There is no antecedent basis for this limitation in the claims.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1-5, 7 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,612,977 to Staskin et al.

(claim 1) Staskin a device for placing a reinforcing tape in a tissue body, comprising an introducer **44** having an elongated body defining a cavity (Fig. 5) and also comprising pulling means at both ends of the body, and means for cutting

comprising an aperture (col. 17, ll. 1-5). The perforations would allow passage of a cutting tool.

(claims 2-5) Perforations to allow separation of the two portions of the sheath will have the perforation holes extend transversely from the longitudinal axis of the body (Figs. 3A,3B), which would allow placement of the tape in the body.

(claim 7) The device includes sling tape **42**.

(claim 8) Staskin discloses the use of a guide **54D** (Fig. 14A).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Staskin et al, as applied in the rejections above.

Staskin discloses semi-rigid needles **60** attached to the pulling portions of the elongated body but is silent with regards to the needles being integral with the ends of the elongated body. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the needles be integral with the ends of the elongated body since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *In re Larson*, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965).

15. Claims 8-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Staskin et al, as applied in the rejections above, and in view of US 6,423,080 to Gellman et al.

Staskin discloses the use of a guide/dilator **54D** but is silent with regards to the use of a curved guide. However, the use of curved guide during the delivery of a sling implant is well known in the art. For instance, Gellman discloses a curved guide, as shown in Fig. 54, which is used to delivery a sling implant. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the guide of Gellman with the device of Staskin because the guide will allow the sling implant to be delivered directly to the surgical site. Furthermore, Gellman also discloses the use of a trocar with the delivery guide (col. 21, ll. 43-49).

With regards to the shape of the distal end of the guide, Gellman discloses the guide having a curved shape. Gellman does not disclose the guide having an helicoidal shape. However, one of ordinary skill in the art would have found it obvious to modify a curved shape distal end to a helicoidal shape distal end since it has been held that changing the shape of a working part involves only routine skill in the art. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

With regards to the angular sector range of the arcuate portion of the guide (or the helicoidal portion), one of ordinary skill in the art would have found it obvious to arrive at the recited ranges since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges

involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezzo whose telephone number is (571) 272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erezzo/
Examiner